Office Action Dated: 04/10/2006

REMARKS

Docket Number: TW-0004

Reconsideration and allowance are requested in view of the amendments and remarks herein.

The Examination

Claims 1 and 9 were objected to because of various informalities. We have corrected these informalities according to the Examiner's suggestions.

Claim 21 has been cancelled in response to the Examiner's objection that it is independently distinct from the invention as originally claimed.

Claims 1, 2, 4-6, 22, and 23 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent 5,788,634 to Suda et al. ("Suda") in view of US Patent 5,649,543 to Hosaka et al. ("Hosaka"). We have amended independent claims 1, 22, and 23. Independent claim 1 supports dependent claims 2 and 4-6.

Claims 7-11 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Suda in view of Hosaka, and further in view of U.S. Patent 6,616,613 to Goodman ("Goodman"). We have amended independent claim 1 that supports these claims, and have also amended claims 5, 8, 10, and 11.

Claim 14 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Suda in view of Hosaka, and further in view of U.S. Patent 6,537,225 to Mills ("Mills"). We have amended independent claim 1 that supports this claim, and have also amended claim 14.

Claims 18 and 20 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Suda in view of Hosaka, and further in view of U.S. Patent 4,718,428 to Russell et al. ("Russell"). We have amended independent claim 1 that supports these claims, and have also amended claim 18.

Claims 18-20, 24, and 25 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Suda in view of Hosaka, and further in view of U.S. Patent 6,095,985 to Raymond et al. ("Raymond"). We have amended independent claim 1 that supports claims 18-20, and have also amended claim 24 which supports claim 25.

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Amended and New Claims

In order to more clearly describe the invention, we have amended claims 1, 4, 5, 8, 9, 10, 11, 14, 18, and 22-24; added claim 26; and deleted claims 2, 6, and 21. With these amendments claims 1, 4, 5, 7-11, 14, 18-20, and 22-26 are pending in this Application.

Specifically, independent claims 1 and 22-24 now describe a hand-held device comprising an optical module <u>operating in a reflective mode</u> and featuring an optical sensor that detects <u>reflected</u> radiation from the patient to generate first set of information. An electrical sensor featuring an electrode pair measures a second set of information from the patient. A processing module <u>mounted in the hand-held component</u> processes the first and second sets of information to make a blood pressure measurement. Support for these amendments is found throughout the specification, particularly in Figs. 1 and 2B and their associated text, e.g., paragraphs [35] and [39] which describe an <u>on-board processing component within</u> the hand-held device; and paragraphs [40] and [42] which describe a <u>reflective</u> optical configuration.

The Prior Art

The examiner cited the following prior art references in the Office Action mailed February 23, 2006.

Suda describes a multi-purpose sensor featuring a 'gripper' that includes an electrode pair and an optical system operating in a transmission mode. The electrode pair and the optical system generate information that is processed with an external controller to make a blood pressure measurement.

Hosaka describes a blood pressure monitor that uses optical and electrical sensors to measure a pulse wave propagation time. A CPU analyzes the propagation time to determine a patient's blood pressure.

Goodman describes an optical sensor that measures an optical signal. A processor analyzes the optical signal along with calibration information to determine blood pressure, which is then sent wirelessly to a computer system.

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Mills describes an optical system for monitoring physiological characteristics of a patient that includes an optical tissue probe, a position sensor for measuring a patient's height compared to a level of their heart, and a controller for processing signals from the optical system. The system measures the patient's blood pressure and other properties by analyzing measurements from the optical system.

Russell describes a system that measures pulsatile fluid flowing though a flexible tube (e.g., a patient's artery) using a 'waveform sensing cuff'.

Raymond describes a health-monitoring system based on a 'multi-parametric' monitor that periodically and automatically measures physiological data from sensors in contact with a patient's body.

Patentability Over The Prior Art

An interview concerning the Present Application was held on April 13, 2006 at the U.S. Patent and Trademark Office. Applicant Banet is very grateful for the time and consideration provided by Examiner Mallari. During the interview, Applicant Banet demonstrated to Examiner Mallari a device embodying the invention. The prior art references, particularly Suda and Hosaka, were discussed during the interview. And even though no consensus was reached as to the patentability of the claims, there was a discussion as to the lack of motivation, suggestion or teaching to combine the references, and to the fact that the prior art references fail to disclose the invention of the amended claims. As set forth in more detail below, we believe that Suda and Hosaka, along with the other references, do not disclose the invention of the amended claims.

First, although all of the parties are well aware of Section 2143 of the MPEP, it is worth repeating for the Present Application.

Section 2143 of the MPEP states:

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success.

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Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The prior art fails to disclose the invention recited in our new and amended claims. Specifically, independent claims 1 and 22-24 describe a hand-held device featuring a reflective-mode optical geometry and an on-board processor. In contrast, Suda's 'gripper' includes a light-emitting device mounted on a first arm ('4' and '1', respectively, in Fig. 4), and a diametrically opposed light-receiving device mounted on a second arm ('5' and '2', respectively). The light-emitting and light-receiving devices are 'provided in a face-to-face relationship' to operate in a transmission-mode geometry (paragraph 2, lines 5-6). Signals generated by these optical devices are 'sent to a measuring unit (not shown) via lead wire 13' to be processed outside of the gripper (paragraph 3, lines 20-22).

The Examiner's secondary reference, Hosaka, fails to cure the deficiencies of Suda, as it provides no teaching of a hand-held component, an on-board processing component, nor a blood pressure measurement that relies on a reflection-mode optical geometry. Instead, Hosaka describes an <u>undefined</u> 'CPU ('1' in Fig. 1) that processes transmission-mode measurements made, e.g., by a conventional pulse oximetry sensor <u>attached</u> to the ear or finger, as described in Fig. 9 and in col. 8, lines 1-10. The reference makes no reference to a specific form factor, focusing instead on a method used to calculate blood pressure from a pulse wave velocity.

Thus even if combined, which is done mainly through hindsight reconstruction, Suda and Hosaka still yield a device that relies on a transmission-mode optical measurement and has no on-board processor. Our invention offers several advantages over this combination. As described in our paragraphs [33] and [35], a hand-held device that includes a reflective-mode optical configuration and on-board processor results in a portable, easy-to-use system that unobtrusively measures blood pressure from nearly any part of the patient's body. To facilitate a measurement, there are no wires to external controllers, as taught by Suda, nor is it required to attach any sensors to the patient, as taught by Hosaka.

Mills and Goodman, taken alone or combined Suda and Hosaka, also fail to teach all the features of the independent claims. Mills, for example, provides no teaching of an on-board processor. The devices shown in Figs. 3-8 only include optical components, and require the external signal-processing electronics shown in Figs. 11-15 to make a measurement. Similarly, Goodman fails to describe an on-board processor: the various devices described throughout the lengthy patent specifically send data through a cable (13) or a wireless interface to an external processing device (14) (see, for example, paragraph 9, lines 10-13). Raymond, taken alone or combined with Suda and Hosaka, also fails to teach all the features of the independent claims. The reference provides no teaching of a reflective-mode optical geometry, and even lacks a teaching of measuring blood pressure. Perhaps more importantly, neither Mills nor Goodman nor Raymond say anything about a blood pressure measurement based on analysis of optical and electrical signals. The references, therefore, fail to cure the deficiencies of Suda and Hosaka.

In summary, the Examiner's primary references applied to the independent claims --Suda and Hosaka-- taken alone or in combination, fail to disclose all the claims' limitations. The secondary references --Goodman, Mills, Raymond, and Russell-- fail to cure these deficiencies. We therefore submit that the independent claims of the present invention, as amended, are significantly removed from the Examiner's references. The dependent claims are even further removed. We therefore respectfully request a notice of allowance for all the pending claims of the present Application.

Respectfully Submitted,

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